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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,620	02/20/2004	Liwen Jiang	14769US02	7208

23446 7590 03/22/2007
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EXAMINER

KUMAR, VINOD

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/783,620

Applicant(s)

JIANG ET AL.

Examiner

Vinod Kumar

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-9,13,15 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7-9,13,15 and 17-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02/20/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1, 3, 7-9, 13, 15, and 17-29 are pending. Claims 1, 3, 7-9, 13, 15, and 17-29 are examined in the instant Office action. All previous objections to specification and drawings have been withdrawn in light of amendments to the specification and drawings. All previous claim rejections not set forth below have been withdrawn in view of claim amendments. This action is made FINAL.

Claim Rejections - 35 USC § 112

2. Claims 1, 3, 7-9, 13, 15, and 17-29 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA construct comprising a promoter sequence capable of expressing target proteins in transgenic plant comprising a seed-specific promoter sequence which is operably linked to a target sequence comprising at its N-terminal end a vacuolar sorting determinant signal, such as proaleurin signal, wherein C-terminal end of target sequence is operably linked with TMD of BP-80 protein, which is further operably linked with CT of a α -TIP protein, does not reasonably provide enablement for a DNA construct comprising a seed-specific promoter sequence capable of directing expression in plant seeds which is operably linked to *any* target sequence comprising at its N-terminal end *any* signal sequence, wherein C-terminal end of target sequence is operably linked with *any* TMD of *any* protein, which is further operably linked with *any* CT of *any* protein, for the reasons of

record stated in Office action mailed on August 22, 2006. Applicants traverse the rejection in the paper filed on January 9, 2007.

Applicants argue that claim 1 has been amended to limit that second DNA sequence having a transmembrane domain sequence of BP-80 and a cytoplasmic tail sequence of BP-80 or α -TIP. Applicants argue that Office action of August 22, 2006 explicitly admits that such an embodiment is enabled by the specification (response, page 16, lines 6-13).

Applicant's arguments were fully considered but were not found to be persuasive. Applicant's attention is drawn to page 5, item 7, lines 5-6 of Office action mailed on August 22, 2006, wherein it is clearly stated that C-terminal end of target sequence when operably linked with TMD of BP-80 protein, which is further operably linked with CT of a α -TIP protein is enabled. It is also stated that the specification does not provide enabled for C-terminal end of target sequence being operably linked with TMD of BP-80 protein, which is further operably linked with CT of BP-80 protein. Furthermore, Applicant's attention is drawn to page 7 of Office action mailed on August 22, 2006, wherein Office has explicitly given reasons why TMD and CT sequences derived from the same protein or TMD and CT sequences derived from proteins other than BP-80 and α -TIP are not enabled in the instantly claimed construct.

The amended claim 1 still reads on using TMD of BP-80 with CT of BP-80, and accordingly claim 1 and claims dependent thereon are not enabled for the reasons discussed in detail in previous office action and further outlined as above.

Accordingly, the rejection is maintained.

3. Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed on August 22, 2006. Applicants traverse the rejection in the paper filed on January 9, 2007.

Applicants argue that vector pBI121 was well known to people skilled in the art and readily available to the public when present application was filed. Applicants cite Appendix B filed in the paper of January 9, 2007 to support their arguments. Applicants further argue that vector pSB130 was known to people skilled in the art when present application was filed. Applicants cite Appendix D filed in the paper of January 9, 2007 to support their argument (response, page 6, lines 7-29)

Applicant's arguments were fully considered and found to be partially persuasive. It is noted that binary vector pBI121 was available to the public at the time of filing instant application (GenBank Accession No. AF485783). However, it is also noted that vector pSB130 was not readily available to the public at the time of filing. Also, the complete sequence of pSB130 is not disclosed to the public at the time of filing. Citation of appendix E cannot substitute the requirement of biological deposit for vector pSB130. In the absence of such disclosure, it is maintained since the biological material vector pSB130 is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the

public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials as discussed in the previous Office action.

Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 103

4. Claims 1, 3, 7-9, 13, 15, and 17-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al. (The Journal of Cell Biology, 143:1183-1199, 1998) in view of Altenbach et al. (Plant Molecular Biology, 13:513-522, 1989) and Goddijn et al. (Trends Biotechnol. 13: 379-387, 1995), for the reasons on record stated in the Office action of August 22, 2006. Applicants traverse the rejection in the paper filed January 9, 2007.

Applicants argue that that Jiang et al. do not suggest that a seed-specific promoter could function in plant after being linked to the construct as claimed in the current claim 1. Applicants further argue that Altenbach et al. do not teach that the phaseolin promoter sequence in the regulatory region, which is one of many sequences, is seed-specific and could regulate a foreign gene expression specifically in plant seeds by itself. Applicants further argue that there is no motivation or suggestion in Jiang et al. or Altenbach et al. to modify the construct of Jiang et al. with a seed-specific promoter to achieve a construct in claim 1 of the present application. Applicants further argue that Goddijn al. do not teach a seed-specific promoter sequence or the use thereof in a DNA construct, and general teachings that seeds can be used as

"bioreactors" does not provide the specific motivation or suggestion required to modify the construct of Jiang et al. with a seed-specific promoter to obtain a DNA construct as claimed by claim 1 (response, page 19, lines 4-28; page 20, lines 1-7).

Applicant's arguments were fully considered but were not found to be persuasive. Applicants are reminded that phaseolin promoter taught in Altenbach et al. is well known in the art of seed-specific promoters. This has been further emphasized through the teachings of Altenbach et al. Furthermore, it is important to note that Altenbach et al. vividly teach a phaseolin genomic clone comprising a promoter which is able to drive expression of a nucleotide sequence encoding a protein (e.g. Brazil nut) in a seed-specific manner.

Applicants are reminded that claims do not require teaching any nucleotide sequence including "phaseolin promoter sequence in the regulatory region" as argued by Applicants. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Nevertheless, Altenbach et al. does teach the genomic clone comprising seed-specific-promoter and provide the necessary citations for complete nucleotide sequence of the genomic clone (see page 514, last paragraph, 1st column).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, Jiang et al. teach all the elements required to practice the invention, except the seed-specific promoter. Office maintains that given Goddijn et al. clearly teach the importance of using seeds as bioreactors in expressing any protein of interest, it would have been obvious for one of the ordinary skill in the art to have been motivated to express any protein of interest in seeds by modifying Jiang et al. construct with any seed-specific promoter including the one taught by Altenbach et al. to produce a foreign protein of interest at commercial scale with reasonable expectation of success.

Thus it is maintained that the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

5. Claims 1, 3, 7-9, 13, 15, and 17-29 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink that reads "David H. Kruse". The signature is written in a cursive style, with the first name "David" and last name "Kruse" clearly legible, and the middle initial "H." written in a smaller, less distinct script.